

# **EXHIBIT G**



## Evaluation and Surgery for Stress Urinary Incontinence: A FIGO Working Group Report

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**Aims:** To review available evidence regarding evaluation and treatment of stress urinary incontinence (SUI) and provide recommendations for management of urinary incontinence under specific conditions determined by the International Federation of Gynecology and Obstetrics (FIGO) Working Group. **Methods:** The FIGO Working Group discussed the management of SUI during meetings and assessed the evidence. The search of evidence was performed using MEDLINE<sup>®</sup> and Cochrane databases as well as additional searches from societies and major organizations for additional guidelines and recommendations and hand searches from bibliographies. Initial searches from 1985 to December 31, 2012 extended until July 15, 2015. After review, recommendations are made based on levels of evidence according to the recommendations from Oxford EBM Center. **Results:** Initial evaluation of SUI consists of history and physical examination; cough stress test, evaluation for urinary tract infections (UTI), assessment of urethral mobility, and post-void residual volumes (LOE 5). Urodynamic studies are not necessary to evaluate patients with uncomplicated SUI (LOE 1a). Conservative treatment should be tried prior to surgery and more importantly in areas of low resources (LOE 5). Midurethral slings (MUS), pubovaginal (traditional suburethral) slings (PVS), and Burch colposuspension are effective in treating SUI (LOE 1a). Patients with SUI with ISD or UUI appear to have lower cure rates than patients without (LOE 2-4). There are limited data on surgical outcomes under limited resources (LOE 5). **Conclusions:** MUS, PVS, and Burch colposuspension are effective treatments for SUI. Evidence for recommendations to treat patients in underserved low resource areas is lacking. *Neurourol. Urodynam.* © 2016 Wiley Periodicals, Inc.

**Key words:** burch colposuspension; intrinsic sphincter deficiency; level of evidence (LOE); midurethral slings; pubovaginal sling

### INTRODUCTION

Stress urinary incontinence (SUI) is defined by the International Urogynecological Association (IUGA) and International Continence Society (ICS) joint report on the terminology for female pelvic floor dysfunction as "the complaint of involuntary urine loss of urine on effort or physical exertion or on sneezing or coughing."<sup>1</sup> It is a common condition affecting nearly half of all women suffering from urinary incontinence and responsible for having a negative impacting on their quality of life.<sup>2-4</sup>

The estimated worldwide number of women aged  $\geq 20$  years projected to have SUI or MUI in 2018 are 153.5 and 52.5 million, respectively.<sup>5</sup> Currently, there are many therapeutic options to treat urinary stress incontinence making it difficult for the practicing specialist to choose among them. It is customary to try nonsurgical therapy prior to initiating surgical treatment for SUI. Most algorithms recommend nonsurgical treatment first and then surgical treatment for failures or patients refusing nonsurgical treatment. There are many different types of conservative therapies to treat SUI; however, none have been found to be consistently more effective than pelvic floor muscle training (PFMT).<sup>6,7</sup>

There are various surgical procedures available to treat SUI. Although the introduction of the tension free vaginal tape (TVT)

sling in 1996 by Ulmstern, there has been a shift in the treatment of SUI from the preferential Burch colposuspension or traditional suburethral sling also known as a pubovaginal sling (PVS) to the midurethral sling (MUS).<sup>8</sup> More recently, there have been further changes in the types of MUS employed to treat SUI. Initially, there was the retropubic TVT sling followed by the transobturator tape (TOT) sling and now the single incision minisling (SIMS). Each procedure is associated with specific risks and benefits and surgeons often face making decisions based on conflicting evidence.

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In this clinical opinion paper, we report the conservative and surgical treatment options for stress urinary incontinence. The FIGO Working Group "Pelvic Floor Medicine and Reconstructive Surgery" discussed the management of urinary stress incontinence during a series of meetings; the literature was reviewed and consensus opinion in areas where either the data were poor or not of good quality was provided. The FIGO Working Group addresses SUI, a common problem affecting women and facing obstetricians and gynaecologist to treat worldwide with the objective of providing some consensus where the evidence was poor. The Working Group was tasked with specific clinical conditions in women with SUI to provide consensus for each (Fig. 1).

#### MATERIALS AND METHODS

In this clinical opinion paper, we report the conservative and surgical treatment of SUI. The FIGO Working Group "Pelvic Floor Medicine and Reconstructive Surgery" discussed the management of SUI during a series of meetings and communications. The literature was reviewed at these meetings after searching MEDLINE<sup>®</sup>, Cochrane database and other expert opinion and recommendations from national and international societies. The following keywords (MeSH terms) grouped into the following syntax were used: "urinary incontinence," "stress urinary incontinence surgery," "incontinence surgery," "intrinsic sphincter deficiency," "mixed urinary incontinence," "tension free vaginal tape sling," "sling surgery for urinary incontinence," "transobturator tape sling," "pubovaginal sling," "Burch colposuspension," "mini slings," "single incision slings," "urodynamic studies," and other subject headings. Initially, this search was done from 1985 to December 31, 2012 and then extended until July 15, 2015. Emphasis was placed on

randomized trials and trials with follow-up of at least 12 months. Additional communication and discussions took place by correspondence until consensus opinions were reached. The document is presented as a consensus statement and not as a systematic review.

Most definitions within this paper are in accordance to the IUGA/ICS joint report on the terminology for female pelvic floor dysfunction.<sup>1</sup> Stress urinary incontinence is defined as the "complaint of involuntary loss of urine on effort or physical exertion or on sneezing or coughing," whereas mixed urinary incontinence (MUI) is the "complaint of involuntary loss of urine associated with urgency and also with effort or physical exertion or sneezing or coughing."<sup>1</sup> Storage symptoms refer to increased daytime urinary frequency, nocturia, urgency, whereas voiding symptoms refer to slow stream, straining to void, feeling of incomplete emptying, urinary retention, and others.<sup>1</sup>

For purpose of determining a need for further evaluation in patients complaining of SUI, these are designated as either having uncomplicated or complicated SUI.<sup>9</sup> An uncomplicated patient is one that has a history of SUI without further storage symptoms and absence of voiding symptoms. This indexed patient does not have a history of recurrent urinary tract infections (RUTI), no prior extensive pelvic surgery or prior surgery for stress incontinence and no medical conditions that can affect the lower urinary tract.<sup>9</sup> Upon clinical examination, there is absence of prolapse beyond the hymen, presence of urethral hypermobility, and absence of urethral abnormalities. Stress incontinence has been observed on provocation, the post-void residual urine volume is normal (less than 150 ml), and screening for a urinary tract infection has been negative.<sup>9</sup>

Patients not fulfilling the uncomplicated category are classified as having complicated SUI. These patients have

1. What should be considered the basic preoperative evaluation required assuming all resources are available?
2. What should be considered the basic preoperative evaluation required assuming limited resources?
3. Are urodynamic studies required in all patients prior to surgery?
4. Surgical treatment under specific circumstances or potential risk factors were there are unlimited resources\*
  - a. Patients with pure SUI
  - b. Patients with mixed urinary incontinence
  - c. Patients with concomitant POP
  - d. Patients with ISD
  - e. Patients with previous failed continence surgery
  - f. Patients with immune compromised conditions
  - g. Patients 65 years of age and older
  - h. Patients with morbid obesity
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  - h. Patients with morbid obesity

SUI = stress urinary incontinence, POP = pelvic organ prolapse, ISD = intrinsic sphincter deficiency

\*Most tests and types of surgeries are available

^ Restriction of tests and surgeries

Fig. 1. Specific inquiries regarding the evaluation and surgical treatment of stress urinary incontinence with and without intrinsic sphincter deficiency examined.

additional storage and voiding symptoms, RUTI, poorly controlled diabetes mellitus, neurological disease affecting the lower urinary tract, prolapse beyond the hymen, absence of urethral hypermobility ( $<30^\circ$  deflection) or PVR  $\geq 150$  ml.

The term unlimited resources refers to the availability of routine medications (e.g., antibiotics, antimuscarinics, analgesics, etc.), tests or imaging (e.g., urine culture, UD, cystoscopy, ultrasound, etc.), surgical materials (TVT, TOT, SIMS, surgical instruments and sutures, etc.), and services and trained personnel (anaesthesiologist, trained surgeon, nursing, aseptic environment, etc.) that are commonly available in most major hospitals or surgical centers throughout the industrial and developed world. It is understood that not all hospitals will have every gadget available. Limited resources refers to the absence of resources listed under unlimited resources and in reference to situations encountered in the developing countries.

No ethical approval was sought for this study. Results are summarized under headings corresponding to the tasks queried by FIGO from the Working Group with the purpose of providing a consensus opinion (Fig. 1).

Where appropriate, the different treatments are described based on the literature evidence (EBM levels 1a–5).<sup>10</sup> The evaluation and degree of difficulty involved are also discussed as expert opinions (level 5) and summarized with recommendations (Grade of Recommendation A–D, abbreviated as grade A–D).

## RESULTS

### Evaluation

The initial goal of the evaluation is to determine whether the patient has uncomplicated SUI (predominant SUI symptoms, a history without having extensive pelvic, or anti-incontinence surgery, absence of POP beyond the hymen, confirmation of incontinence (consistent with SUI), absence of a UTI, normal PVR ( $\leq 150$  ml), and urethral hypermobility) or complicated SUI (not fulfilling uncomplicated SUI criteria).<sup>9</sup> Ultimately, the evaluation should provide a diagnosis and information to assist in planning treatment.<sup>11,13</sup>

#### What Should be Considered the Basic Preoperative Evaluation Required Assuming all Resources Are Available?

A standardized process to evaluate patients complaining of SUI is currently lacking; however, specialized societies and health organizations have published recommendations.<sup>9,11–14</sup> Goals of the evaluation process are to confirm the diagnosis of and characterize SUI, evaluate for additional lower urinary tract symptoms (LUTS), and assess for comorbidities that may affect prognosis, counseling, and treatment.<sup>11</sup> The major components of the evaluation process include; history, and clinical (physical) examination (general and focused) and investigations (non-invasive and invasive).<sup>9,11</sup>

### Diagnosis of SUI

Diagnosis is usually based on:

1. History, for example, urological and general
2. Clinical examination
  - a. Physical examination, for example, general and focused
  - b. Cough stress test (demonstration of leakage)

- c. Urethral mobility
- d. Post-void residual urine volume (depending on history)

3. Urinalysis (dipstick has high specificity)
4. Investigations, for example, urodynamics, cystoscopy

**History.** Patient history should include a focused urological history to characterize or determine the type of urinary incontinence that is bothersome to the patient (stress, urgency, coital, etc.). A focused urological history after assessing for urinary incontinence associated with a loss of urine on physical exertion, sneezing, and so on, should include questions about recurrent urinary tract infections, bladder storage (frequency, urgency, urgency incontinence, continuous leakage, nocturia, etc.), and emptying (slow stream, straining to void, feeling of incomplete emptying, etc.) functions.<sup>9,11,13</sup> Further questioning on the frequency and severity of incontinence, degree of bother, and impact on quality of life is essential for counseling and planning treatment. After the urological history, a thorough general history is important. The general history includes medical (diabetes, neurological disorders, etc.), obstetrical, surgical (anti-incontinence, POP surgery, etc.), bowel, sexual, and medications. Based on history alone, the uncomplicated SUI patient is characterized by a history of leaking urine associated with physical exertion (sneezing or jumping) in the absence of urgency or voiding symptoms (retention, difficulty emptying, etc.); prior anti-incontinence, POP, or radical pelvic surgery; recurrent urinary tract infections; and medical conditions that can affect the lower urinary tract.

Evaluation of symptoms and assessment of impact on quality of life can be facilitated by the use of validated questionnaires.<sup>9,11</sup> Using validated questionnaires can provide additional information about other contributing symptoms, severity, and degree of bother. Overall, validated questionnaires are recommended in research, and although useful, not necessary for routine care (LOE 5).

**Clinical examination.** The clinical examination refers to assessing a set of elements that are included in the physical examination (general and focused), cough stress test, degree of urethral mobility, and post-void residual urine volume measurement.<sup>9</sup>

**Physical examination.** The purpose of the physical examination is to determine the presence or absence of factors affecting the incontinence and its treatment (LOE 5, Grade D). Genitourinary examination should include assessment for a urethral diverticulum, fistula, estrogenic status, vaginal masses, vaginal volume, and prolapse.<sup>11</sup> A focused neurological examination assessing sensation and bulbo-cavernosus reflex is useful.<sup>11</sup> Assessment of pelvic floor muscle (PFM) strength can be useful in deciding non-surgical treatment (LOE 5). PFM evaluation can easily be performed by instructing the patient to squeeze (contraction) their PFM and vaginally palpating the effect. Although PFM evaluation is strongly encouraged, it is not considered necessary to diagnose uncomplicated SUI<sup>9,13</sup> (LOE 5, Grade D).

Evaluation for POP can be done using one of several clinical quantification systems. The Baden Walker classification (1971) was one of the first classification systems used.<sup>15</sup> The POP-Q system introduced in 1996 has become the internationally accepted standard for reporting POP in research today.<sup>16</sup> Although the POP-Q system is objective and specific for reporting POP, its complexity limits routine use. Because of the complexity of the POP-Q, a more simplified version has been



developed (S-POP-Q).<sup>17</sup> Because of the simplicity of the S-POP-Q system, it is recommended for routine clinical practice over the more robust standard POP-Q system<sup>11</sup> (LOE 5, Grade D recommendation). It is recommended to assess all pelvic support compartments (anterior, apical, and posterior), since POP beyond the hymen can produce a relative obstruction of the urethra<sup>9</sup> (LOE 5, Grade 4).

**Cough stress test.** The primary purpose of the cough stress test is to objectively demonstrate leakage from the urethra simultaneously with a cough.<sup>9,11</sup> The cough stress test is usually performed with the patient having a comfortably full bladder or following retrograde filling to a volume of at least 300 ml<sup>18,19</sup> (LOE 4). Visualization of urine leaking from the urethra simultaneously with a cough is diagnostic of SUI, whereas absence of leakage or delayed leakage is considered a negative cough test and warrants further testing.<sup>9,11</sup> The test can be performed in the supine or standing position, but if done supinely and the result is negative, the test must be repeated in the standing position with the bladder filled to at least 300 ml.<sup>9,11,18,20</sup> If there is prolapse present, the reduction of the prolapse is recommended<sup>9,21</sup> (Grade 4). The supine empty stress test (SEST) to assess for ISD has not been found to be a reliable test, but when negative (no leakage), it has been shown to have a negative predictive value of 90% for ruling out a low valsalva leak point pressure (VLPP) on urodynamic testing and thus absence of ISD.<sup>22</sup> A cough stress test should be performed on all patient initially being evaluated for SUI<sup>9,11,13</sup> (LOE 1, Grade A).

**Urethral mobility.** Urethral hypermobility refers to the excessive downward displacement of the urethra during Valsalva.<sup>11</sup> It is widely accepted that urethral hypermobility is associated with SUI; however, this association is neither regular nor has there been a universally accepted definition.<sup>11</sup> Urethral hypermobility is defined as a urethral displacement  $\geq 30^\circ$  from the horizontal when the patient is in the supine lithotomy position while straining.<sup>23</sup> The cotton swab test (Q-tip test) has been the traditional test to assess urethral hypermobility, although there are other ways to assess hypermobility including ultrasonography, visualization, and measurement of POP-Q point Aa.<sup>24</sup> The use of point Aa is not recommended at this time.

The Q-tip test is performed by inserting a lubricated cotton-tipped swab into the urethra and bladder and then gently pulling back from inside the bladder until resistance is met (indicating at the bladder neck position).<sup>11,23</sup> The patient is then asked to strain and measurement taken from resting to maximum straining angle (positive test if  $\geq 30^\circ$  difference).<sup>23</sup> Urethral hypermobility is not diagnostic of SUI; however, a lack of urethral mobility has associated with a nearly twofold increase in the failure of midurethral sling (MUS) treatment of SUI.<sup>25</sup> Urethral mobility assessment is recommended (LOE 4–5, Grade D).

**Postvoid residual urine volume measurement.** There is no agreement on what constitutes a normal post-void residual (PVR) volume, but most support a PVR volume greater than 150 ml as abnormal.<sup>9,11,26</sup> The American College of Obstetrics and Gynecology (ACOG) and American Urogynecologic Society (AUGS) in a joint committee opinion, recommend performing a PVR evaluation of patients evaluated for SUI symptoms.<sup>9</sup> Similarly, IUGA/ICS in a joint report also recommend evaluating for a postvoid residual urine measurement, but in women with symptoms of voiding dysfunction or with a history of RUTI.<sup>11</sup> The residual urine may be measured by either catheter or ultrasound. It is recommended to perform PVR measurements in patients complaining of SUI symptoms (LOE 5, Grade D).

**Urinalysis.** Evaluation of the urine for the presence of a urinary tract infection (UTI) is necessary in all patients

complaining of SUI<sup>9,11,13</sup> (LOE 4, Grade D). A urine dipstick is recommended over a microscopic urinalysis because of cost (Grade D). A urine culture is another option, but preferably reserved to confirm a positive urinalysis.<sup>27</sup> Screening the urine for a UTI is recommended as an initial step in any patient complaining of SUI<sup>9,11,13</sup> (LOE 4–5, Grade D).

**Investigations.** Urodynamic testing (UD) is composed of a battery of tests that include uroflowmetry, cystometry, pressure flow study, urethral pressure profilometry, as well as assessment of PVR and possibly VLPP.<sup>11</sup> The ultimate role of UD is to establish a baseline understanding of the pathophysiology, to improve choice of treatment and ultimately improve outcome.<sup>9,11</sup> UD is not necessary prior to planning primary surgery in patients with uncomplicated SUI.<sup>9,11</sup> Although patients with uncomplicated SUI have not been found to benefit from preoperative UD, this may not be the case in complicated cases.<sup>11</sup> In patients with uncomplicated SUI, UD was not found to be predictive of surgical outcome.<sup>28,29</sup> Additional testing may include cystoscopy (e.g., patients with previous anti-incontinence surgery or POP surgery with mesh), imaging with ultrasound (previous sling or mesh), CT, or MRI (e.g., pain, previous mesh, microhematuria).<sup>11</sup> In patients with uncomplicated SUI neither the use of UD or other additional testing is necessary prior to planning surgery.<sup>9,29</sup> (LOE 1b, Grade B recommendation). However, in women who have complicated SUI, the determination for needing additional testing like UD may be left up to the clinical judgement of the individual practitioner (Grade D). In cases where the diagnosis is uncertain or pathophysiology unknown, then UD despite limitations as the only test available that can help should be used. In complicated cases UD may be beneficial and is recommended<sup>11</sup> (Grade D).

The basic evaluation for patients initially complaining of SUI symptoms should be a urological and general history, focused genitourinary examination, cough stress test, screening of a UTI, assessment of urethral hypermobility, and a PVR (Grade D).

In patients complaining predominantly of SUI symptoms and found to have an uncomplicated SUI history, non UTI, no significant prolapse (beyond hymen), a positive cough stress test (leakage with cough), and PVR volume  $\leq 150$  ml no additional testing is necessary prior to planning any type of treatment (LOE 3–5, Grade D).

#### What Should be Considered the Basic Preoperative Evaluation Required Assuming Limited Resources?

The basic evaluation of SUI is similar in situations with limited resources as with unlimited resources (Fig. 2).<sup>9,11</sup> The goal is to determine if SUI is uncomplicated or complicated and for surgical planning. Obtain a urological and general medical history. Determine if the patient has a history of RUTI, extensive pelvic surgery (including POP or anti-incontinence), perform a focused genitourinary and neurological examination (e.g., assessing for POP), perform a cough stress test (document incontinence), urinalysis (to identify UTI), and a PVR (exclude retention) depending on symptoms. Examination for urethral hypermobility is helpful in determining if the patient is at higher risk of failure.<sup>25</sup>

In patients with complicated SUI, urodynamic testing is recommended if available (Grade C). However, if UD is not available and the patient has predominant SUI symptoms with a PVR  $< 150$  ml, surgical planning can take place without it, provided the practitioner uses good clinical judgement (Grade D). Because of the inherent risks associate with synthetic materials for erosion, anyone having had prior surgery with mesh or synthetic sling of any type should undergo cystoscopy prior to continence surgery (Grade D).

### Are Urodynamic Studies Required in all Patients Prior to Surgery?

There is lack of universal consensus regarding the role of UD in the evaluation of SUI, whereas some studies support using it, others have failed to demonstrate routine utility.<sup>17,22–24</sup> A recent study has shown that UD is not necessary in uncomplicated patients.<sup>25</sup> Although UD has failed to improve surgical outcome in uncomplicated cases of SUI, this may not be the case in patients with complicated SUI.<sup>26</sup> Urodynamic testing is not routinely recommended in all patients (Grade C). UD is not recommended for surgical planning in patients with uncomplicated SUI (LOE 1a, Grade A). However, UD is recommended in patients with complicated SUI prior to initiating treatment when the underlying diagnosis is yet unknown or concerned with voiding symptoms (Grade C). The ultimate decision for testing prior to initiating treatment should be individualized and left to the practitioner's clinical judgement (Grade C).

### Surgical Treatment of Urinary Stress Incontinence Under Specific Circumstances or Potential Risk Factors Where There Are Unlimited Resources Available

This section summarizes the findings and recommendations to treat SUI under specific circumstances and risk factors assuming all resources available (Fig. 1)

**Surgical treatments for patients with uncomplicated stress urinary incontinence.** A Cochrane review in 2009 found the midurethral slings (MUS), pubovaginal (traditional suburethral) slings (PVS), and Burch colposuspension (BC) to be efficacious in women with SUI.<sup>30</sup> Other studies have independently found these procedures to be effective in treating SUI.<sup>31,32</sup> The cure rate following laparoscopic Burch colposuspension is similar to that with an open BC.<sup>33</sup> Each procedure is associated with its own complexity and types of complications, for example, Burch colposuspension is associated with longer operative times and higher rates of wound infection, hematoma and longer hospital stay but lower rates of longer term side effects than the MUS.<sup>34</sup> Currently, the treatment of SUI with MUS is preferable to the BC and PVS because of similar or superior cures, but with shorter operative times and hospital stay.<sup>31,32</sup> MUS are considered minimally invasive procedures compare to BC and PVS. A recent published systematic review did not favor MUS over BC but favored PVS over BC and MUS over PVS based on cure rate, but stated that ultimate choice should balance adverse events and concomitant surgery.<sup>34</sup>

Both the TVT and TOT procedures have demonstrated similar efficacy treating SUI.<sup>35–45</sup> More recently, a systematic review from SGS and a Cochrane review assessing the use of MUS to treat SUI have both confirmed the efficacy of TVT and TOT procedures.<sup>34,46</sup>

A still less invasive type of MUS is the mini-sling, single incision sling, or single incision mini-sling (SIMS).<sup>47</sup> These SIMS are placed through a single incision and anchored into the obturator fascia. There are several types of SIS available and since the beginning of this project, the TVT Secur has been removed from the market because of lack of efficacy.<sup>48,49</sup> A Cochrane review in 2014 did not have enough evidence to allow reliable comparison with TVT or TOT.<sup>50</sup> However, a systematic review and meta-analysis comparing SIMS to standard MUS did not find significant difference in patient-reported outcome or objective cure after excluding TVT-Secur.<sup>51</sup> However, in that study, there was a higher but non-significant trend toward repeat incontinence surgery. In a recent RCT comparing SIMS to outside-in TOT with 12 months follow-up, there was no difference in subjective or objective outcome.<sup>52</sup> Although

SIMS appear to be effective in the short-term studies and with report similarities to other types of MUS, at this time, long-term outcomes are lacking.<sup>53–55</sup>

There is a limited number of good quality studies with long-term follow-up comparing MUS to Burch colposuspension or PVS or Burch colposuspension to PVS.<sup>56,57</sup> All of these procedures have shown success in the treatment of SUI and are recommended (LOE 1a, Grade A). Choosing between the individual procedures is based on balancing success and complications<sup>34</sup> (LOE 1a, Grade A). Studies providing Level 1 evidence point out that TVT and TOT both have similar cure rates, however, differ in types of complications.<sup>34,35,41,46</sup> TOT compared to TVT has lower rates of bladder perforation, lower rate of vascular or visceral injury, lower blood loss, and a lower mean operative time and less voiding dysfunction, but was associated with higher incidence of groin pain and mesh exposure/extrusion.<sup>46</sup> Based on types and frequency of complication TOT is preferable to TVT, but one cannot be recommended over the other<sup>34,46</sup> (LOE 1a, Grade A). Between the traditional MUS (TVT/TOT) and SIMS, the traditional slings are recommended over the SIMS until we have consistent long-term data (LOE 2, Grade B).

Use of urethral bulking or urethral injections and artificial sphincters (AS) should be reserved for special circumstances based on lack of efficacy with the urethral injections and associated complications with the AS, respectively.<sup>58–62</sup> Both procedures lack randomized trials and long-term follow-up.

**Surgical treatments for patients with mixed urinary incontinence.** There is no difference in the cure rate of SUI symptoms in patients with mixed urinary incontinence (MUI) following treatment with either TVT or TOT.<sup>63,64</sup> There is evidence suggesting of higher rates of urgency and urgency incontinence following treatment with PVS or BC compared to MUS.<sup>65</sup> Patients with MUI undergoing surgery need counseling regarding the higher risks of failure compared to patients with SUI only (Grade C). The overall cure is higher in patients with predominantly SUI symptoms compared to urgency incontinence symptoms.<sup>66,67</sup> Surgery should be discouraged in patients with predominant urgency and urgency incontinence symptoms<sup>67</sup> (LOE 3, Grade C). In patients with MUI, conservative treatment such as behavioral and medical treatment is recommended prior to considering surgery (Grade D). Because of the lack of evidence at this time, it is not clear how to manage MUI effectively, but there are some data that support the MUS over BC and PVS, and TVT over TOT.<sup>63</sup> At this time, a MUS is recommended after a trial of conservative treatment and only in patients without predominant urgency or urgency incontinence symptoms (LOE 3–4, Grade C).

**Surgical treatments for patients with stress urinary incontinence with concomitant pelvic organ prolapse.** The efficacy of continence surgery does not appear to be affected by performing an anti-incontinence procedure at the time of surgery to correct pelvic organ prolapse (POP).<sup>28,68–70</sup> Many surgeons feel that concomitant surgery can jeopardize the outcome of the continence procedure and in many cases may not even be necessary if performing an anterior repair. As suggested by IUGA/ICS, a reduction cough stress test should be performed on all patients with significant prolapse beyond the hymen to evaluate for occult incontinence prior to POP surgery.<sup>11</sup> The MUS, PVS, and Burch colposuspension have all been performed at the time of POP surgery and shown to be efficacious.<sup>71</sup> Both the TVT and TOT have similar efficacy, whereas the PVS has a better outcome compared to BC.<sup>27–29</sup>

Despite recent reports supporting the use of prophylactic anti-incontinence procedures at the time of POP surgery, this

1. History
  - a. Detailed history of current problem - type of leakage, associated lower urinary tract symptoms (LUTS), timing and frequency of leakage, impact and coping strategies.
  - b. Detailed medical history
  - c. Detailed surgical history and history of pelvic radiation
  - d. Medications taking
  - e. Quality of life questionnaires and symptom questionnaires encouraged (Translated validated questionnaires are preferable)
2. Clinical evaluation
  - a. Physical examination – abdomen, vulva, perineum, assessment for prolapse (described using the pelvic organ prolapse quantification (POPQ) system) with valsalva maneuvers, urethra, neurological
  - b. Cough stress test – standing or supine with 300 ml (supine or standing) comfortably full with or without prolapse reduction depending on presence or absence of prolapse – observe for leakage at the time of the cough or valsalva
  - c. Post-void residual – catheterized or ultrasound (< 50–150 ml)
  - d. Urethral mobility – (noting the presence or absence of hypermobility is encouraged) clinically observed urethral hypermobility or Q-tip test  $\geq$  30 degrees or hypermobility observed on ultrasound
3. Laboratory testing
  - a. Urine dipstick or urinalysis
4. Functional evaluation\*
  - a. Urodynamic studies (UDS)
  - b. Video urodynamics (VUDS) – rarely indicated
5. Additional testing (in selected cases only)\*\*
  - a. Cystoscopy – suspect bladder lesion (previous surgery)
  - b. Bladder diary – when having significant storage symptoms
  - c. Pad testing (1 hour or 24 hours) – (mostly research or normal UDS)
  - d. Ultrasound – previous surgery, complicated cases
  - e. MRI – previous surgery, complicated cases
  - f. Other imaging studies

\*UDS recommended when a diagnosis is not possible with just the clinical evaluation or to reinforce the clinical diagnosis

VUDS – not for diagnosis of SUI only

\*\* Additional testing necessary only in specific cases and should not be routinely used

Fig. 2. Sample evaluation—key elements.

practice has not been universally accepted.<sup>68</sup> Although prophylactic anti-incontinence surgery decreased the number of patients having postoperative SUI, it does not prevent SUI in all patients treated and in addition others underwent additional surgery for complications from the anti-incontinence procedure.<sup>71–73</sup>

A recent meta-analysis concluded that only patients with SUI or occult SUI at the time of POP surgery should have an anti-incontinence procedure performed along with the POP surgery.<sup>70</sup> Performing anti-incontinence surgery at the time of POP surgery is recommended in patients with SUI or occult SUI only<sup>70–72</sup> (LOE 1b-3, Grade B).

**Surgical treatments for patients with stress urinary incontinence and intrinsic sphincter deficiency (ISD).** In patients with ISD, the choice of surgery is more challenging. Most experts feel that patients with ISD have a more severe type of urinary incontinence. Besides having more severe symptoms, women with ISD have been found to have lower cure rates following surgery when compared to women without ISD.<sup>22,74</sup> In some studies, the TVT procedure has been associated with better outcomes compared to TOT in patients with ISD undergoing a MUS; however, this is not universally accepted.<sup>75–78</sup> Although many support the use of TVT over the TOT in patients with ISD, a recent RCT found both procedures to have similar efficacy regardless of sphincter function.<sup>34</sup>

At this time, ISD is considered a more severe type of urinary stress incontinence by some and a risk factor for failing continence surgery.<sup>77,79</sup> In patients with ISD, some favor TVT over TOT and PVS over BC, however, there is no consensus.<sup>75,76</sup>

Urethral bulking has been inconsistently effective in treating patients with ISD and long-term data are lacking.<sup>59–62,80</sup> There are not enough data available to comment on the adjustable Reemex sling and the role of artificial sphincters is reserved as an alternative for recurrent incontinence with ISD and poor voiding mechanism<sup>81</sup> (Grade D). In the surgical treatment of ISD, MUS, and PVS are recommended over BC (Grade B).

**Surgical treatments for patients with stress urinary incontinence with previous failed continence surgery.** In patients with previous failed continence surgery or recurrent stress urinary incontinence, a repeat surgery is generally associated with higher failure rates compared to performing a primary procedure.<sup>82</sup> There is currently no consensus on how to best manage failures. Burch colposuspension is helpful but with a cure rate lower than in primary procedure.<sup>83</sup> PVS and MUS are efficacious in patients with recurrent SUI, but less effective than when initially used.<sup>73,84,85</sup> The PVS has been shown to be more effective than the Burch colposuspension in treating patients with recurrent SUI.<sup>85</sup>

The limited data available do not allow for a clear choice between the PVS and MUS in treating patients with recurrent



SUI.<sup>82</sup> Among the MUS procedures, the TVT edges TOT having greater success in treating recurrences.<sup>86–88</sup> Despite the lack of dependable quality data necessary to make a strong recommendation, available level 3 evidence supports recommending PVS or TVT.

Although urethral bulking injections are not as effective as slings, these are less invasive and associated with less major complications and thus often more useful as an alternative or salvage procedure. There are other procedures available to treat recurrent urinary incontinence like the artificial sphincter, adjustable slings, and other injectable and other types of slings; however, because of insufficient reliable data available at the time of this paper, these types of procedures are not discussed further.<sup>89,90</sup> Available data mostly support the use of PVS and TVT as well as Burch colposuspension, TOT, and urethral bulking in patients with recurrent incontinence (Grade C recommendation).

**Surgical treatments of stress urinary incontinence in patients with immune compromised conditions.** Evidence to guide the surgical management of immune compromised patients is currently lacking. In immune compromised patients, the surgeon should be aware of difficulties with tissue healing and risk of infections.<sup>91</sup> MUS involve the use of synthetic material (permanent foreign body) and thus a potential risk for infection and other future complications.<sup>91</sup> Both BC and PVS are associated with risks of wound infection and hernia; however, PVS involves more surgery and potential for infection. Burch colposuspension appears to potentially carry less risks for infection and this is an estimate at best. If a procedure must be chosen a BC is recommended (Grade D).

**Surgical treatments for patients 65 years of age and older with stress urinary incontinence.** Patients 65 years of age and older are at higher risks of having significant medical co-morbidities when compared to patients under the age of 60 years old.<sup>92</sup> These older patients are also at a higher risk of having ISD, poorly functioning detrusor, and inefficient voiding mechanism.<sup>93</sup> There is evidence that continence outcome decreases in these patients and management can be often difficult.<sup>92,93</sup> Midurethral slings, PVS, and Burch colposuspension have been shown to be effective in treating SUI in elderly patients.<sup>92–94</sup>

In the elderly, the ideal procedure to treat SUI needs to be minimally invasive, effective, and avoid obstructive micturition.<sup>94</sup> A MUS is the most logical surgical procedure to treat SUI in elderly patients because it is minimally invasive, can be performed under local anesthesia, and usually there is faster recovery. Between TVT and TOT, a TOT is recommended because of less morbidity and voiding dysfunction associated with it<sup>46</sup> (LOE 3, Grade C).

**Surgical treatments for morbidly obese patients with stress urinary incontinence.** Morbid obesity does not appear to be a significant risk factor for failing surgery to cure SUI.<sup>93,96</sup> Some studies have found a lower cure rate in patients with high BMI compared to normal weight.<sup>93,95</sup> Although cure rates in morbidly obese women are similar to that in normal patients, still surgery in morbidly obese women can be more technically challenging and often associated with greater blood loss and operative time.<sup>93,95</sup> Both PVS and colposuspension are more technically difficult compared to a MUS. Levels 2 and 3 evidence suggest that MUS, PVS, and Burch colposuspension are all effective in treating SUI in morbidly obese women, and no specific procedure has been shown superior to the other.<sup>96</sup> Current evidence does not support the choice of one procedure over the other, however, a MUS may be preferable based on degree of difficulty, operative time, and postoperative morbidity. Although there are no specific studies comparing the different types of procedures in morbidly obese women, a MUS

is recommended because it is more likely to be less technically challenging with less postoperative morbidity (Grade C).

**Surgical treatment of urinary stress incontinence under specific circumstances and potential risk factors when the availability of resources is limited.** In cases with limited resources all recommended optimal treatments are identical to those to practitioners with all resources available. Choice will depend on degree of limitation. It is recommended for patients to undergo treatment with non-surgical methods prior to having surgery. Patient respond to pelvic floor muscle training (PFMT) and may avoid surgery in 30–50%.

**Behavior modification with fluid management and weight reduction.** These are important to try first specifically if the surgical options available are suboptimal. Other forms of non-surgical treatment include pelvic floor physiotherapy (PFPT) with or without biofeedback and electrical stimulation.<sup>11–13</sup> Incontinence pessaries are also helpful. Choices will depend on resources available and in places with very low resources PFMT may be the only alternative.<sup>11–13</sup>

Practitioners are encouraged to use clinical judgment and choose among those surgical options balancing between efficacy and adverse events and avoid procedures with significant downstream consequences<sup>11–13,97</sup> (Grade D).

Under limited resources, procedures like the anterior repair, needle suspension that are no longer recommended to SUI, may be used since they have been known to improve SUI symptoms and usually are associated with minimal adverse events.<sup>97–99</sup> This deviation from what is considered standard practice is only justifiable under extreme situations where the patient is bothered by SUI and would otherwise never have a chance to improve her condition (Grade D).

## DISCUSSION

Patients with SUI should be appropriately evaluated to determine the type of incontinence and any potential risk factor that may have an impact on the success of the treatment.<sup>100</sup>

Obtaining a thorough urological history, performing a genitourinary examination, confirming SUI with a cough stress test, assessing for urethral hypermobility, determining a PVR and screening for a UTI are essential and the absolute minimum in an evaluation.<sup>9,11</sup> Urodynamic testing is not necessary in patients found to have uncomplicated SUI.<sup>9</sup> Not recommended routinely in uncomplicated cases of SUI (LOE1a, Grade A). Urodynamic testing is recommended in complicated cases; however, the decision to use UD is up to clinical judgement of the practitioner and necessity to reach a diagnosis and plan treatment<sup>11</sup> (LOE 2-3, Grade C). Any further discussion concerning UDS is beyond the scope of this paper.

It should be noted that patients with SUI should be offered a trial of nonsurgical treatment with PFMT and depending on the circumstance weight reduction, fluid management, and other non-surgical strategies such as PFPT, biofeedback, electrical stimulation and even pessary prior to surgery.<sup>101–108</sup> Although recent level 1 evidence found surgery to be superior to PFMT, still many patients improved and did not have further need for surgery.<sup>109</sup>

Current reviews on the surgical treatment of SUI support treatment with a MUS, BC, or PVS.<sup>34,45,46</sup> Choice of one procedure over the other is generally dependent on efficacy of the procedure, associated adverse events and indication.<sup>34,46</sup>

Although some systematic reviews support the use of MUS the same as BC, MUS over PVS, and PVS over BC based on operative time, recovery, and complications, as these procedures are nearly equal in efficacy and each only differentiated



TABLE I. Recommended Treatment of SUI Under Specific Circumstances Based on Level of Evidence

Condition	Recommendations		Grade	LOE
	Primary	Optional procedure		
Primary SUI	TOT, TVT	PVS, BC	A	1a
Mixed urinary incontinence	TVT, TOT	PVS, BC	C	3-4
Concomitant POP	TOT, TVT BC	PVS	B	1b-3
ISD	TVT, PVS TOT	BC	B	2-3
		Urethral bulking, TOT, AUS		
Previous failed continence surgery	TVT, PVS BC	TOT, urethral bulking, AUS	C	2-4
Immune compromised conditions	BC	PVS, TVT, TOT	D	5
≥65 years of age	TOT	TVT, urethral bulking, BC, PVS	C	3
Morbid obesity	TOT	TVT, BC, PVS	C	2-3

SUI, stress urinary incontinence; LOE, level of evidence<sup>13</sup>; TOT, transobturator tape sling (out-in and in-out); TVT, retropubic tension free vaginal tape sling; PVS, pubovaginal sling; ISD, intrinsic sphincter deficiency; Urethral bulking, urethral injections; AUS, artificial urethral sphincter; MUS, midurethral sling (both retropubic TVT and TOT); BC, Burch colposuspension.

by the types and frequency of complications.<sup>34,45,46</sup> Since the MUS and PVS have been found to have slightly better cure rate than the BC in patients with recurrent SUI and ISD, it is recommended to perform these procedures in such cases<sup>76,102</sup> (Grade B). Between the different types of MUS, the TVT retropubic approach seems to be more effective than TOT in patients with ISD and thus favored in these patients (Grade B).<sup>75,76,79</sup> However, in patients with primary incontinence and without ISD, both TVT and TOT are effective and the decision of one type of MUS over the other is left up to the surgeon's experience (LOE 1a, Grade A).<sup>29,36,103,104</sup>

Incontinence surgery is not recommended in patients with isolated urgency incontinence, however, may be useful in patients with MUI particularly in those with predominant SUI symptoms.<sup>16,17</sup> Synthetic slings of any type are contraindicated in patients with known urethral injury, fistula or diverticulum. Caution should be paid in placing synthetic slings in immune compromised patients and preferably avoided in an irradiated pelvis. In elderly patients, complicated, lengthy, and obstructive procedures should be avoided. Although the elderly respond well to continence surgery, care needs to be taken since they often have more voiding problems afterward. To lessen obstruction, a TOT is preferred over a TVT in the elderly undergoing a MUS (Grade C).<sup>29,104</sup> The overall cure rate in the elderly is less when compared to younger patients.<sup>92,93,104</sup> In patients with morbid obesity, all attempts should be made at losing weight first, but between surgical options, a MUS is the better choice (Grade C).

The management of SUI under limited resources will depend on the degree of limitation. All recommendations are based on generalizing outcomes from studies done under normative conditions. Under these circumstances patient evaluation may be limited to a history and brief clinical evaluation demonstrating leakage associated with coughing or valsalva. Prior to surgery the patient should be instructed to lose weight and perform PFMT first.<sup>5</sup> In patients with SUI failing PFMT and other forms of pelvic floor physiotherapy, the next step is usually

TABLE II. Summary of Recommendations for Evaluation and Treatment of SUI With or Without ISD

Recommendations	GR
Ideally, patients with SUI should be initially treated conservatively first with PFMT <sup>a</sup>	A
In patients with simple or uncomplicated SUI, a detailed office evaluation should be performed	A
Urodynamic testing is not necessary in patients with uncomplicated SUI	A
Ideally, a MUS should be used to treat uncomplicated SUI undergoing surgical treatment	A
TVT and TOT have similar cure rates in patients with uncomplicated SUI	A
MUS, colposuspension and PVS can be used to treat uncomplicated SUI	A
In patients with ISD, TVT and PVS are more effective than TOT and colposuspension	B
TVT and TOT are recommended over SIS at this time	B
MUS may be better choices to treat patients with MUI compared to PVS and colposuspension	C
MUS, PVS, and colposuspension can be performed concomitantly with POP surgery	C
Prophylactic procedures should not be performed with POP surgery	B
Both TVT and PVS are preferred over TOT and colposuspension in patients with ISD	B
MUS, PVS, and colposuspension are choice in patients with recurrent SUI	C
In immune compromised patients, a colposuspension may be preferable	D
A MUS is preferable to treat elderly patients	C
Urethral bulking can be used to treat failures or to avoid the operating room	D
In limited resource areas, complicated SUI may undergo surgery without UDS evaluation	D
Anterior repair is an option if resources not available in underserved countries	D

GR, grade of recommendation; SUI, stress urinary incontinence; ISD, intrinsic sphincter deficiency; PFMT, pelvic floor muscle training; TOT, transobturator tape sling (out-in and in-out); TVT, retropubic tension free vaginal tape sling; PVS, pubovaginal sling; Urethral bulking, urethral injections; MUS, midurethral sling (both retropubic TVT and TOT).

<sup>a</sup>GR given based on support and not on level of evidence.

surgical. The preferable procedure must be efficacious, safe, available, and performable with the resources available (Grade D). If possible, patients in areas of limited resources can be transferred to obtain better care. Procedures known to carry long-term risks such as use of permanent grafts should be avoided in places with restrictions, unless expertise will be available to manage possible future complications (Grade D). Under such circumstances with limited resources, management of SUI is probably best treated with best procedure available (Grade D). Cystoscopy is recommended following all surgical procedures to treat SUI that may compromise the bladder or ureters<sup>11</sup> (Grade A).

## CONCLUSION

In conclusion, despite the lack of consistent high-level evidence to provide strong recommendation for all specific conditions, there is enough evidence available to provide a reasonable guide in most circumstances. Recommendations for evaluation and management of SUI, ISD, and other specific circumstances are summarized in Tables I and II. Overall basic office evaluation suffices for most cases of uncomplicated SUI.

There is robust evidence supporting the use of MUS, PVS, and Burch colposuspension to treat SUI; however, the evidence supporting one procedure type over the other is not nearly as strong. Although TVT and PVS may be more effective in patients with ISD and recurrent incontinence, the evidence is not consistent and less for other types. Overall, the majority of recommendations are Grade A regarding treatment of uncomplicated SUI and Grade C and D or complicated SUI and other conditions and the later in consistence with the lack of good evidence in most subcategories of incontinence specifically when addressing cases with limited resources.

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